K032517

MAY 1 8 2004

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Mansour Consulting LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
3-Phone: (770) 777- 4146
4-Fax: (678) 623- 3765
5-Contact Person: Jay Mansour
6-Date summary prepared: March 29th, 2004
7-Device Trade or Proprietary Name: MEDSAFE ClickSafe™ Safety Antistick Syringe with hypodermic needle
8-Device Common or usual name: Safety Syringe with hypodermic needle
9-Device Classification Name: Syringe, AntiStick, with hypodermic needle
10-Substantial Equivalency is claimed against the following device:

- VANISHPOINT SYRINGE from RETRACTABLE TECHNOLOGIES, INC. 510k# K946219, cleared at that time under the tradename of Pop-N-Lok syringe.

11-Description of the Device:

The MedSafe ClickSafe™ Syringe is a 3cc, sterile, non-toxic, non-pyrogenic, disposable, manually activated, plunger type, Anti-Stick syringe with integral hypodermic needle, as detailed within this submission and in relevant patents.

The primary intended use of the device is to give safe and accurate subcutaneous and intramuscular injections. Its secondary intended use is to retract and contain the contaminated needle after injection and render the syringe inoperable for further injections while not introducing any additional steps to the one-handed operating method, for the purpose of aiding in the prevention of accidental needle stick injuries.

The MedSafe Safety Syringe operates in the same manner as standard hypodermic syringes, prior to the actuation of the safety mechanism. The *plunger* is retracted as the medication is drawn up to the desired amount. Next, the medication is administered to the patient in the usual way, by inserting the *needle* into the patient's tissue and depressing the *plunger*. Figure 1 shows the syringe in its configuration after the medication has been expelled and before the actuation of the safety mechanism. The various parts are identified therein, including the *plunger*, the *boot*, the *body* (barrel) and the *needle*, all of which are common to standard syringes. The difference is that the *boot* in the MedSafe syringe is rupturable and the *plunger* is hollow. The *needle* is held by the *needle hub*, which is in turn held in place by the *base*, which also serves to seal the medication in the syringe. The *base* is held in place at its plunger-end by an

interior shelf in the *body*. There is a *spring* around the *needle* which is held in place by the *nose* and bears against the *needle hub*. Once the medication is expelled, the continued depression of the *plunger* causes the *base* (which contains the entire needle assembly) to slide, thereby compressing the *spring*. Continued depression of the *plunger* drives the *needle hub* against the *nose* and pushes the *base* over the *needle hub*. As the *needle hub* exits the *base*, it stretches the *boot* which subsequently ruptures. At this time, the compressed *spring* propels the *needle* and *hub* into the hollow *plunger*, where it is caught and secured by the *needle catch* (integral to the *plunger*). Thus, the "dirty" *needle* is securely held out of harm's way inside the *plunger*, as depicted in Figure 2.

After use, the healthcare worker disposes of the syringe in a sharps container in accordance with OSHA regulations.

The following size variations are listed below. Refer to main section of the submission for complete details.

Syringe	Needle	Product Reorder No.
3cc	25G x 5/8"	SB3506
	25G x 1"	SB3510
	23G x 1"	SB3310
	22G x 1"	SB3210
	22G x 1 ½"	SB3215
	21G x 1"	SB3110
	21G x 1 ½"	SB3115
	20G x 1"	SB3010
	20G x 1 ½"	SB3015

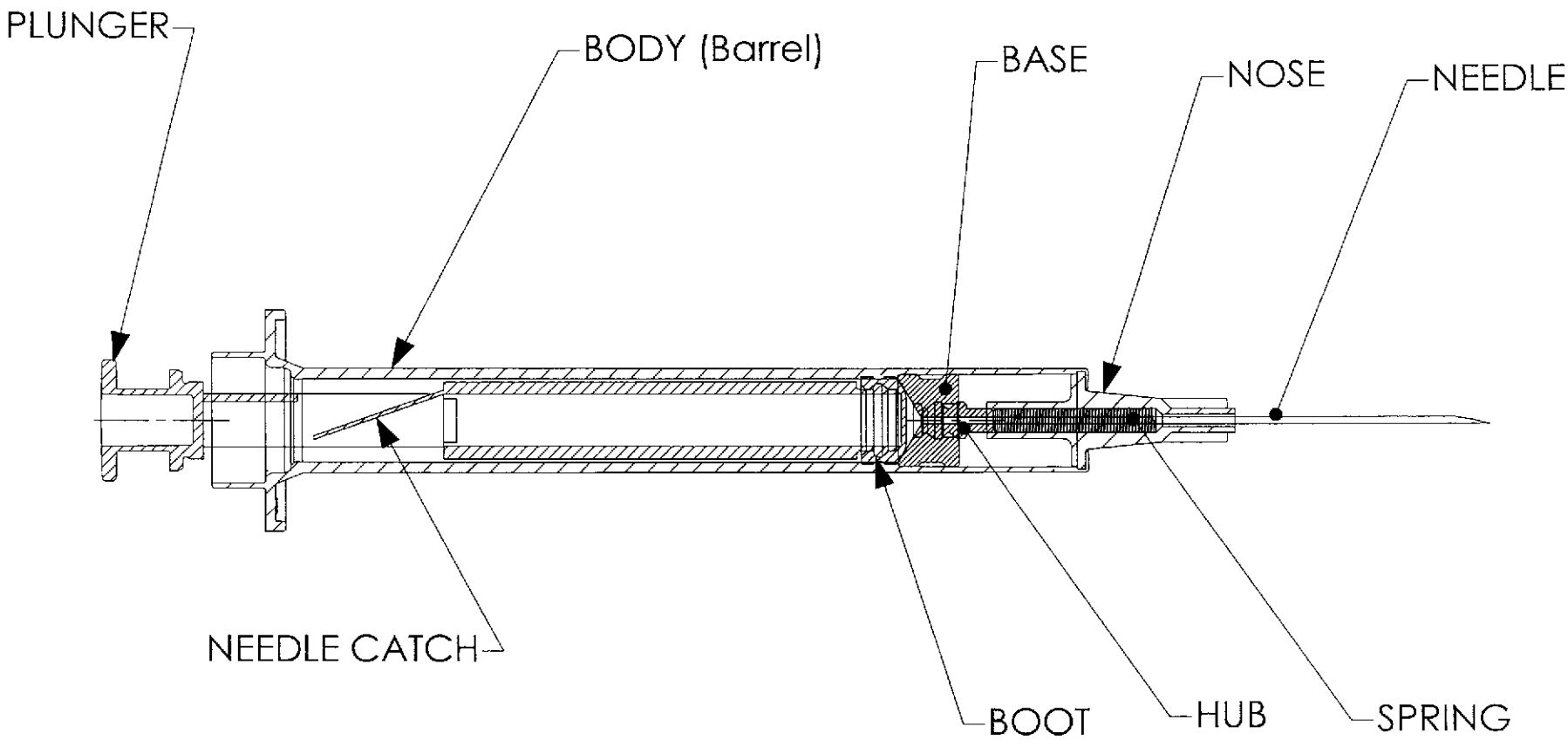


FIG. 1 MedSafe Safety Syringe
After Medication Expended and Before Safety Mechanism Actuated

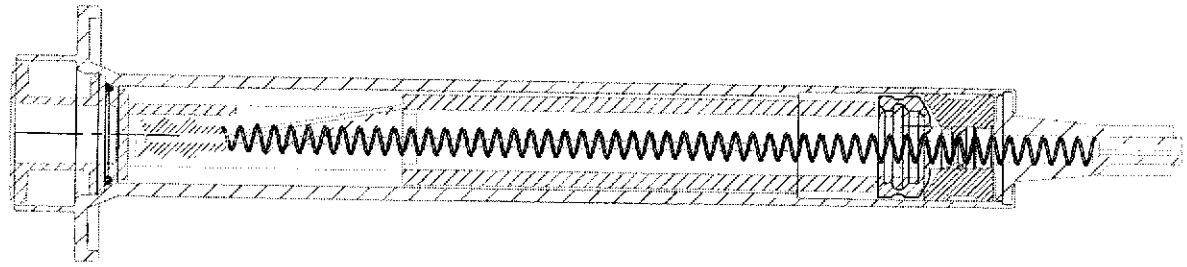


FIG. 2 MedSafe Safety Syringe After Safety Mechanism Actuated

K030517

12-Intended use of the device: (refer to FDA form attached)

The MedSafe ClickSafe™ Syringe is a 3cc, sterile, non-toxic, non-pyrogenic, disposable, manually activated, plunger type, Anti-Stick syringe with integral hypodermic needle.

Its primary intended use of the device is to provide a safe, accurate and reliable method of injecting medication into a patient, subcutaneous as well as intramuscular.

Needle retraction is activated by the syringe user AFTER REMOVING THE NEEDLE FROM THE PATIENT FIRST

Its secondary intended use is to retract and contain the contaminated needle after injection and render the syringe inoperable for further injections while not introducing any additional steps to the one-handed operating method, for the purpose of aiding in the prevention of accidental needle stick injuries that would be occurring between removing the needle from the patient and disposing it into sharps container.

13-Safety and Effectiveness of the device:

This device is safe and effective as the predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate device. Refer to the explanations/details within the main submission.

K032577

FDA file reference number	K946219
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Identical
Sterility	Similar
Biocompatibility	Similar
Mechanical safety	Identical
Chemical safety	Similar
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Similar
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2004

MedSafe Technologies LLC
C/O Mr. Jay Mansour
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, Georgia 30022

Re: K032517
Trade/Device Name: MedSafe™ ClickSafe Safety Antistick Syringe with Hypodermic Needle
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: March 29, 2004
Received: April 6, 2004

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

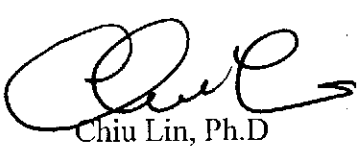
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032517

Indications for Use

510(k) Number (if known): K032517

Device Name: MedSafe ClickSafe™ Safety Antistick Syringe with hypodermic needle

Indications For Use:

The MedSafe ClickSafe™ syringe is a 3cc sterile, non-toxic, non-pyrogenic, disposable, manually activated, plunger type, anti-stick syringe with integral hypodermic needle.

Its primary intended use and indication for use is to provide safe, accurate and reliable method of injecting medication into a patient, subcutaneous as well as intramuscular. Needle retraction is activated by the syringe user after removing the needle from the patient first.

Its secondary intended use and indication for use is to retract and contain the contaminated needle after injection and render the syringe inoperable for further injections while not introducing any additional steps to the one-handed operation method, for the purpose of aiding in the prevention of accidental needle stick injuries that would be occurring between removing the needle from the patient and disposing it into the Sharps container.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Steve Runner for ADW 5/13/04
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032517